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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,882	03/19/2004	Stephen James Field	0119/0034	7153
21395	7590	10/26/2006	EXAMINER	
LOUIS WOO LAW OFFICE OF LOUIS WOO 717 NORTH FAYETTE STREET ALEXANDRIA, VA 22314			JAWORSKI, FRANCIS J	
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/803,882

### Applicant(s)

FIELD ET AL.

### Examiner

Jaworski Francis J.

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/15, 8/19/04(IDS).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 - 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/15, 8/19/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 4, 7 - 8, 13 – 14, 16 –17 are rejected under 35 U.S.C. 102(b) as being anticipated by William (US5211627). William teaches an elongated thermoplastic plastic catheter 10 formed by extrusion to have an inner layer portion 18 and a thinner outer layer portion 16 forming part of the surface of the device, the outer layer 16 being free of gas bubbles (since there is no liquid therein to form bubbles, akin to air in a room being 'gas-bubble free'), the inner layer 18 having microbubbles therein once liquid is introduced and a forward pressure applied to the air channel by syringe. These bubbles would be found circumferentially about the inner portion in the tip region without a congregating preference, and would be found in a continuous region along the distal length of the device past the mixing orifice. Note also that William acknowledges that formation of bubbles in the inner layer is a function of air syringe pressure. Hence in a withdrawal phase fluid i.e. if the syringe plunger is withdrawn, air would be sucked into the thinner outer portion and at least some bubbles would form about the orifice and none in the inner layer.

Since the inner and outer layers are co-extruded, the outer layer with 16 included may be construed as thicker than the wall of the inner layer comprising the wall

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of the central tube, and as noted above, under negative pressure the outer layer would contain at least some bubbles drawn by suction of fluid thereinto. Such a device, William being a hysterosalpingographic device also capable of sampling suction per cols. 3 – 4 discussion, would be capable of suction sampling of an embryo whereupon the bubble formation would stop and the sampling region be bubble free due to the aforementioned effect.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over William in view of Tickner (US4265251) since whereas the former is silent as to microbubble size save to instruct that this is dependent upon orifice dimension and pressure drop thereacross, it would have been obvious in view of the latter to produce microbubbles in the 1 – 150 micron range since these sizes are most useful in terms of visibility and ability to circulate.

Claims 1 – 11 and 13 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Bosley et al (US5201314 and Jones et al (US6506156) and Rammler (US5327891), alone or further in view of Sarkis et al (US5921933) or Onwumere et al(US5250649).

In the case of Bosley et al , col. 7 lines 21 – 24 together with lines 56 – 60 suggest that an extruded catheter layer may have embedded gases or microencapsulants. Bosley otherwise suggests variously an outer plastic layer 1410 over the inner layer and/or multiple layers per Fig.15 – 16. In the case of Jones et al suggestion is made to provide an extrusion coating 18 of voids or microspheres together with 14 also formable as an extrusion, see col. 4 lines 55 – 56. Whereas the former do not literally state that the gas/microencapsulant/voids are ‘ gas bubbles’ the latter Rammler patent suggests extrusion of an attachable outer catheter layer with microbubbles introduced prior to extrusion. Accordingly the former may be thought of as in supplement to each other regarding extrusion of differing portions of the echogenic catheter and the latter confirming that microbubbles would literally be included in such a

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device since an extrusion of a microbubble-containing partial outer layer is taught in the latter.

Alternatively, if 'extrusion' be considered to be limiting in the sense of 'co-extrusion of all layers, then it would have nonetheless been obvious in view of Sarkis et al col. 3 lines 43 – 48 to co-extrude either an internal or external echogenic layer together with another layer of non-echogenic type (Sarkis et al per se pertaining to echogenic particles as opposed to microbubbles), or in view of Onwumere et al col. 6 lines 17-18 that since radiopaque catheter portions were well-known to be coextrudable with the catheter proper, it would have been obvious to do so in the case of the former teachings.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as alternatively applied as applied to claim 1 above, and further in view of Koulik (US7014610) since col. 7 lines 41 – 49 of the latter teach that porous plastic microspheres such as polyethylene microspheres are an obvious echogenic alternative to unencapsulated or other microbubble forms.

### Patentability Assessment

Three lines of argument are presented:

The William –based argument is predatory upon broad wording and is directed to co-extrusion of a dual channel catheter operable so as to selectively form microbubbles in either of the inner or outer of the coextruded layers.

The Bosley +Jones et al+ Rammler argument poses that if 'extrusion' as pertains to a co-extrusion of layers is considered to be a method limitation which is non-limiting on the structure of layered product, then the art as teaches extruded coatings and extrusion of catheter layers having voids and extrusion of partial layers for attachment would result in the final product of a layered catheter having an inner or outer layer of microbubbles or microvoids.

The B+J+R, further in view of Sarkis et al or Onwumere et al poses specifically that further teachings of co-extrusion of an echogenic particle layer or analogous radioopaque layer with the catheter proper would render the claimed invention obvious if extrusion meaning co-extrusion of layers is accorded patentable weight.

Hence patentability is opposed at this time.

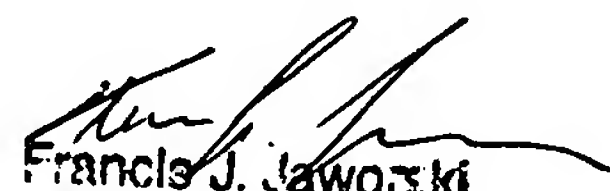
The following art is cited to complete the record as pertains to echogenicity and/or gynecologic sampling devices:

Brustad et al (US2004/0230119), Abae (US6290672), Mills (US6723052).

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

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Francis J. Jaworski  
Primary Examiner